



JAN 28 2004

January 16, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by PhytoPharmica, (a Division of Integrative Therapeutics, Inc.) at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. PhytoPharmica wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pantethine Plus™	Pantethine Plus™ also contains pantethine, a precursor of coenzyme A (CoA). CoA is involved in 70 enzymatic pathways, including cholesterol synthesis. Pantethine modulates the action of several enzymes, including 3-hydroxy-3 methylglutaryl CoA (HMG-CoA) reductase.* Pantethine inhibits the activity of HMG-CoA reductase; this enzyme plays an important part in the pathway of cholesterol synthesis.*	Pantethine

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/16/04

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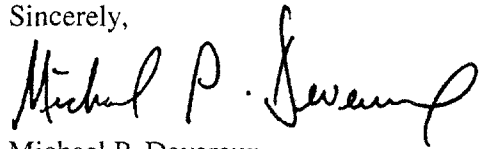
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Pantethine Plus 29p

825 CHALLENGER DRIVE
GREEN BAY, WI 54311-8328
920-469-9099
TOLL FREE 800-553-2370
FAX 920-469-4418
FAX TOLL FREE 888-311-5657
WWW.PHYTOPHARMICA.COM

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and "P." as a middle initial.

Michael P. Devereux
Chief Financial Officer



January 17, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pantethine Plus™	A year-long trial with pantethine was conducted in 24 individuals. The treatment was well tolerated with no subjective complaints or detectable side effects. Blood lipid assays repeated after 1, 3, 6, 9, and 12 months of treatment revealed consistent benefit for retaining healthy cholesterol levels that are already within normal limits.*	Pantethine

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Robert C. Doster

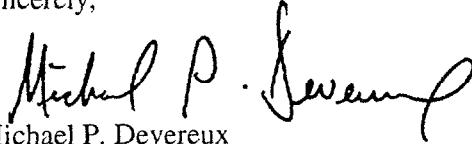
Title: Senior Vice President of Scientific Affairs

Date: 1/17/04

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Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is written in a cursive style with a large, stylized "M" and "D".

Michael P. Devereux
Chief Financial Officer



January 18, 2004

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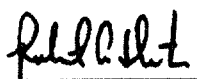
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pantethine Plus™	In another study, the effect of pantethine (various mg doses daily for 3 to 6 months) was evaluated in 72 individuals. The results demonstrated that pantethine was tolerated well and retained healthy cholesterol levels that were already within normal limits.*	Pantethine

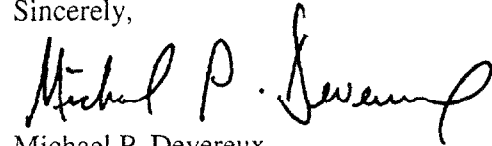
I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: 
Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 1/18/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with a large, stylized "M" and "D".

Michael P. Devereux
Chief Financial Officer



January 19, 2004

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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pantethine Plus™	Phytosterols: Helps reduce cholesterol absorption from food*	Proprietary Phytosterol Blend beta sitosterol, campesterol, stigmasterol, brassicasterol, and other plant sterols

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

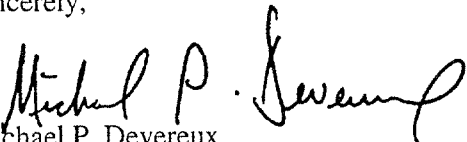
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/19/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,



Michael P. Devereux
Chief Financial Officer